Food and Drug Administration, HHS

leptostomum, C. nassatus, and brevicapsulatus, Cylicodontophorus spp., Cylicostephanus spp. including calicatus, C. goldi, C. longibursatus, and C. minutus, and Petrovinema poculatum; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae)— Parascaris equorum; Hairworms (adults)-Trichostrongylus axei; Largemouth Stomach Worms (adults)-Habronema muscae; Bots (oral and gastric stages)-Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae)—Dictyocaulus arnfieldi; Intes-Threadworms (adults) tinal Strongyloides westeri; Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

- (ii) Tapeworms—Anoplocephala perfoliata; Large Strongyles (adults)-Strongylus vulgaris (also early forms in blood vessels), S.edentatus (also tissue stages), S. equinus, Triodontophorus spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp., Cylicodontophorus spp.; Small Strongyles—fourth-stage larvae: Pinworms (adults and fourth-stage larvae)—Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae)— *Parascaris* equorum; Hairworms (adults)—Trichostrongylus axei; Largemouth Stomach Worms (adults)-Habronema muscae; Bots (oral and gasstages)—Gasterophilus Lungworms (adults and fourth-stage larvae)—Dictyocaulus arnfieldi; Intestinal Threadworms (adults)— Strongyloides westeri; Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.
- (3) *Limitations*. For oral use only. Do not use in horses intended for human consumption.

[68 FR 55309, Sept. 25, 2003, as amended at 69 FR 49808, Aug. 12, 2004; 70 FR 65835, Nov. 1, 2005]

§ 520.1199 Ivermectin, pyrantel, and praziquantel tablets.

- (a) Specifications. Each chewable tablet contains:
- (1) 34 micrograms (mcg) ivermectin, 28.5 milligrams (mg) pyrantel pamoate, and 28.5 mg praziquantel;
- (2) 68 mcg ivermectin, 57 mg pyrantel pamoate, and 57 mg praziquantel;
- (3) 136 mcg ivermectin, 114 mg pyrantel pamoate, and 114 mg praziquantel; or
- (4) 272 mcg ivermectin, 228 mg pyrantel pamoate, and 228 mg praziquantel.
- (b) *Sponsors*. See No. 051311 in §510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Administer monthly according to body weight as follows:
- (i) 6 to 12 lb: one tablet as described in paragraph (a)(1) of this section.
- (ii) 12.1 to 25 lb: one tablet as described in paragraph (a)(2) of this section.
- (iii) 25.1 to 50 lb: one tablet as described in paragraph (a)(3) of this section
- (iv) 50.1 to 100 lb: one tablet as described in paragraph (a)(4) of this section.
- (v) Greater than 100 lb: use the appropriate combination of tablets.
- (2) Indications for use. Prevents canine heartworm disease by eliminating the tissue stage of heartworm larvae (Dirofilaria immitis) for 1 month (30 days) after infection and for the treatment and control of roundworm (Toxocara canis, Toxascaris leonina), hookworm (Ancylostoma caninum, Uncinaria stenocephala, Ancylostoma braziliense) and tapeworm (Dipylidium caninum, Taenia pisiformis) infections.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 65052, Nov. 7, 2006]

$\S\,520.1200$ Ivermectin, fenbendazole, and praziquantel tablets.

- (a) Specifications. Each chewable tablet contains either:
- (1) 68 micrograms (μg) ivermectin, 1.134 grams fenbendazole, and 57 milligrams (mg) praziquantel; or
- (2) 27 μg ivermectin, 454 mg fenbendazole, and 23 mg praziquantel.